

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA)	
AND THE STATE OF CALIFORNIA,)	
EX REL. STEVEN HIGGINS)	Civil Action No. 11-cv-02453-JNE-SER
)	
Plaintiffs,)	
)	
v.)	
)	
BOSTON SCIENTIFIC)	
CORPORATION)	
)	
Defendant.)	
)	

**MEMORANDUM IN SUPPORT OF
RELATOR’S MOTION TO COMPEL**

Pursuant to Local Rule 7.1(b)(1)(C), Relator submits this memorandum in support of his contemporaneously-filed motion to compel, in which Relator asks the Court to compel Defendant Boston Scientific Corporation (“BSC”) to produce to Relator a privilege log that will allow Relator to determine whether BSC’s assertions of privilege have merit. Alternatively, and as a consequence of not providing a privilege log that comes anywhere close to meeting the requirements of the law, Relator seeks an order compelling BSC to produce the underlying documents themselves.

I. PROCEDURAL BACKGROUND

Relator filed this lawsuit in August 2011. (Dkt. 1). BSC filed a motion to dismiss. (Dkt. 61). The Court, while rejecting most of BSC’s arguments, granted its motion to dismiss without prejudice. *United States v. Bos. Sci. Corp.*, 2017 WL 3732099 (D. Minn. Aug. 29, 2017). Relator filed a Second Amended Complaint in September 2017. (Dkt. 98). BSC again moved to dismiss.

The Court denied BSC's motion in its entirety in December 2017. *United States v. Bos. Sci. Corp.*, 2017 WL 6389671 (D. Minn. Dec. 13, 2017).

A. The Factual Allegations In The Operative Complaint¹

In May 2008, BSC obtained approval from the Food and Drug Administration ("FDA") for two medical devices called Cognis and Teligen, both of which are implantable cardiac defibrillator devices and are designed to, *inter alia*, regulate irregular heartbeats by delivering an electric "shock" to restore a normal rhythm. (Dkt. 98 at ¶¶ 5, 61, 219).

Unbeknownst to the FDA, Cognis and Teligen suffered from very significant design defects. Specifically, both devices utilize various components, such as set screws, seal plugs, and headers, as part of the wiring mechanism that delivers the above-described electronic shock. *Id.* at ¶¶ 3, 63. The design defects present in these components led to the malfunctions including both oversensing (delivering a powerful electric shock when it was not necessary) and undersensing (failing to deliver a shock when needed). *Id.* at ¶¶ 99–101. Given the critical importance of a defibrillator to treat an abnormal heart rhythm, these problems resulted in severe and life-threatening injuries to patients in whom the devices were implanted. *Id.* at ¶¶ 72–76. Relator witnessed such patient harm firsthand. *Id.* at ¶¶ 181–187.

BSC knew about the problems before the FDA approved the devices in May 2008 and before launching Cognis and Teligen in the United States in August 2008. In February 2008, BSC launched the devices in Europe. *Id.* at ¶¶ 5, 77, 93. BSC received reports of problems with the devices in Europe, including problems with the set screw and header. *Id.* ¶ 94. Thus, while the

¹ Given that the scope of discovery is driven by the allegations in the operative complaint, this background section is derived from the allegations in the Second Amended Complaint. *See Godfrey v. State Farm Fire & Cas. Co.*, 2019 WL 586675, at *3 (D. Minn. Feb. 13, 2019) (granting motion to compel in relevant part where "it is equally apparent that the discovery that State Farm seeks is relevant to the factual allegations of Plaintiffs' complaint").

FDA was still reviewing the applications for Cognis and Teligen, BSC knew about the critical problems but failed to inform the FDA as required by law. *Id.* at ¶¶ 104–110.

In August 2008, BSC elected to launch the devices in the United States notwithstanding its knowledge of the problems from the European launch and still without notifying the FDA about the problems as required by law. *Id.* at ¶¶ 13, 122. Unsurprisingly, within days of the launch in the United States, BSC began receiving adverse event reports, *i.e.*, reports of the devices malfunctioning due to the design defects. *Id.* ¶¶ at 123, 133–135. The set screw and header problems ultimately resulted in the recall of the device in July 2009. *Id.* at ¶¶ 172–175.

Relator alleges, *inter alia*, that BSC’s misconduct induced the FDA to (1) initially approve the devices and (2) not recall the devices sooner than it did, *i.e.* that the products would have been recalled sooner than July 2009 had the FDA known the truth. *Id.* at ¶¶ 215–220. As a result, BSC caused the submission of false or fraudulent claims for reimbursement for the defective devices to be submitted to the government, including Medicare, Medi-Cal² and other federal health care programs.

II. THE FACTS UNDERLYING BSC’S DISCOVERY VIOLATIONS

The United States (the “Government”) conducted an investigation into Relator’s allegations. In connection with its investigation, the Government sought documents from BSC. During the investigation, BSC produced certain documents to the Government and withheld or redacted certain documents on privilege grounds. BSC conducted a privilege review relating to

² Medi-Cal is the State of California’s Medicaid Program. (Dkt. 98 at ¶ 26).

the documents it withheld or redacted. Unbeknownst to Relator, BSC created a privilege log in connection with that review.

After the Government investigation concluded, Relator served Requests for Production on BSC. The first request sought the documents BSC had previously produced to the Government. BSC produced those documents to Relator between May 8–21, 2018. Despite its legal obligation under Rule 26(b)(5)(A) to timely provide information sufficient to allow Relator assess BSC's claims of privilege, BSC did not produce a privilege log (as noted, Relator was unaware of the existence of the privilege log BSC had prepared in connection with the Government's investigation).

After conducting considerable review of BSC's initial production, and an initial review of BSC second production in October 2018, Relator began to suspect that BSC was withholding documents on privilege grounds. On December 5, 2018, Relator wrote to BSC as follows:

[W]e write to request a privilege log for the production of documents provided thus far. We have noted that many documents in the production are redacted, thus indicating that a privilege review has been undertaken, either in response to our RFPs, or in response to the initial subpoena from the government, or both. Regardless of what caused the privilege review, we specifically request that you provide your privilege log as soon as reasonably possible. Relator is of course aware that the log would need to be supplemented as additional productions are made, but it would be helpful to the efficient conduction of this litigation to have what is presently available, so that Relator can make an initial determination regarding whether any privilege-related presently exist.

Exhibit 1 at 2. BSC responded in a manner suggesting that while it conducted a privilege review with regard to the Government's investigation, no privilege log had been created, but that BSC would endeavor to produce a log to Relator: "[W]ith regards to your request for a privilege log, we note that the only privilege review that has been undertaken was in response to the subpoena from the government. Therefore, we are willing to proceed with preparing a privilege log for documents withheld or redacted from the May 2018 production." *Id.* at 1.

On January 3, 2018, BSC wrote to Relator and provided a privilege log identifying withheld or redacted documents relating to BSC's May 2018 productions. In its cover letter, BSC admitted that it had previously created a log in connection with these documents at the time BSC produced the documents to the Government. *See* Exhibit 2 (“[T]his privilege log was originally prepared in connection with the government’s investigation.”). BSC also advised Relator that the log did not identify any documents withheld or redacted in connection with any other document productions by BSC, *i.e.*, BSC made clear that the log only covered its May 2018 productions. *Id.*

On January 31, 2019, BSC made a third production of documents. Like the October 2018 production, this production was not accompanied by a privilege log, despite BSC's legal obligation to produce same. On February 21, 2019, Relator again raised BSC's failure to timely produce a privilege log, and sought BSC's agreement to produce “rolling privilege logs,” *i.e.*, privilege logs to accompany each production.

BSC has not provided a privilege log for its October 2018 or January 2018 productions. Aside from the general obligation to provide a privilege log when withholding otherwise responsive documents, we believe that prior to deposing any particular individual, BSC is obligated to produce a privilege log with regard to any documents it is withholding that relate to that individual . . . Therefore, we would like to discuss when BSC will produce an updated privilege log to reflect the October 2018 and January 2019 productions (and future productions).

Exhibit 3 at 3. BSC responded, *inter alia*, that it was willing to meet and confer on this issue. *Id.* at 2 (“[W]e are willing to meet and confer regarding your request for rolling privilege logs.”).

On February 26, 2019, BSC wrote a letter to Relator agreeing to produce rolling privilege logs. Exhibit 4 at 1 (“[W]e anticipate making rolling productions of privilege logs in the same order that you have identified for the responsiveness review.”).

As of March 2019, BSC had produced responsive documents for the first 18 custodians (out of a total of 28 custodians). Notwithstanding its representation regarding the production of

rolling privilege logs, BSC produced no such logs. On March 27, 2019, Relator sought to meet and confer with BSC regarding this lack. Exhibit 5 at 5 (“Relator would like to discuss BSC’s intentions regarding when it expects to update its privilege log in connection with the documents BSC has produced with regard to the first 18 custodians.”).

On April 1, 2019, the parties met and conferred on, *inter alia*, the lack of rolling privilege logs. BSC was unable to provide its position regarding its failure to produce rolling privilege logs. *Id.* at 2 (April 2, 2019 email from Relator to BSC confirming that “BSC was unable to provide its position as to . . . [p]roduction of a privilege log for the custodian document productions.”).

On June 14, 2019, BSC finally produced a privilege log for the document productions it made between October 2018 and May 2019. *See* Exhibit 6.

On June 18, 2019, the parties briefly discussed the privilege log deficiencies/dispute during a teleconference with the Court.

On June 19, 2019, Relator outlined the deficiencies in a detailed email to BSC. *See* Exhibit 7 at 4–5.

On June 21, BSC took the position that Relator had waived his opportunity to object to the contents of the January 3rd privilege log. *Id.* at 3 (“We consider your inaction to constitute a waiver of your objections to BSC’s January privilege logs.”).

Relator advised BSC on June 26 that absent BSC’s agreement to remedy the deficiencies in its January 3rd privilege log, Relator intended to seek relief from the Court. *Id.* at 2. BSC responded on June 27 and reiterated its position that Relator had waived his right to object to the content of the January 3rd privilege log. *Id.* at 1 (“BSC maintains that Relator’s failure to raise these issues earlier is inexcusable and warrants no further response on our part.”). The instant motion followed.

III. LEGAL ANALYSIS

Federal Rule of Civil Procedure 26(b)(5)(A) provides that a party wishing to withhold information that is otherwise discoverable on the basis of a privilege, that party must “describe the nature of the documents, communications, or tangible things not produced or disclosed—and do so in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim.” As is the case here, parties typically fulfill the requirements of this rule by producing a privilege log. “[T]he privilege log is a convention of modern legal practice designed to conform with the requirements of Federal Rule of Civil Procedure 26(b)(5).” *Bartholomew v. Avalon Capital Group, Inc.*, 278 F.R.D. 441, 447 (D. Minn. 2011).

As described above, BSC has produced two privilege logs in this case: the January 3rd Privilege Log (as amended on January 15th), and the June 14th Privilege Log. Both of these privilege logs contain numerous inadequacies, such as:

- Failing to identify which sender/recipient of an email or document was acting as an attorney for the purposes of the attorney-client privilege (*see, e.g.*, Exhibit 8 at pg. 20, Reference No. 126) (emphasis added); *see also* Exhibit 9 (a copy of the document with the beginning Bates stamp TEMP-BSC00104128, which appears to be a copy of July 15, 2008 the Minutes of BSC’s key Field Action Committee, the substance of which is entirely redacted, from the little information left unredacted, appears to not have involved any attorneys);
- Claiming that an attachment to an email is privileged because the parent email is privileged, but failing to provide either the Bates number of the allegedly privileged parent email or the privilege log reference number of the allegedly privileged email (*see, e.g.*, Exhibit 8 at pg. 28, Reference No. 178) (emphasis added);

- Failing to provide substantive descriptions of the documents on the privilege log and/or failing to properly evaluate the substantive applicability of the privilege claim (*see, e.g., id.* at pg. 5, Reference No. 27 (emphasis added))³
- Failing to provide the date on which a privileged communication took place as opposed to the date when a document was created (*see, e.g., id.* at pg. 28, Reference No. 178) (emphasis added); and
- Failing to provide the actual name of the author of a document that is claimed to be privileged (*see, e.g., id.* at pg. 193, Reference No. 1164) (emphasis added).

The privilege log entry for Exhibit 9, TEMP-BSC00104128, exemplifies the egregiousness of BSC's inadequate privilege log. Reference No. 880 on page 144 of the privilege log claims that the redacted portions of this document "contains information provided to counsel to facilitate the rendition of legal advice regarding product performance," but the log does not specify who that counsel was, when that privileged communication took place, or explain why the minutes of a meeting that apparently did not involve counsel at the time could later be shielded from production by the attorney-client privilege. Given that this document was generated following a meeting of this key committee only a few weeks before the Cognis and Teligen products were launched in the United States, it is especially concerning that BSC's privilege log entry for this document and claim of privilege are so threadbare.

As the Court instructed the parties during the June 18 status conference, a privilege log exists to allow a judge to make a ruling based on the log itself without having to review documents

³ The "privilege description" of this log entry is "[e]mail chain between employees and counsel providing information to facilitate the rendition of legal advice regarding a field event," and BSC has apparently withheld the entirety of this email chain. Relator's position is that either BSC needs to provide a more substantive description of this email chain, or it needs to produce these documents in a format that show the underlying information while redacting the privileged communications.

ex parte. See also *Honeywell Intern. Inc. v. Furuno Elec. Co.*, 2013 WL 2385224, *3 (D. Minn. May 30, 2013) (“The intendment to Rule 25(b)(5)(A) is clear: the opposing party should be able, from the entry in the log itself, to assess whether the claim of privilege is valid.”) (internal citations omitted). The above-noted inadequacies with BSC’s January 3rd Privilege Log do not allow Relator (or the Court) to assess BSC’s claim of privilege. See *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 2015 WL 9861106, at *4 (D. Minn. Oct. 5, 2015) (noting that a log was deficient where it “failed to provide an adequate description of the documents as well as any indication as to who the individuals were that were named on the log”); *Nw. Airlines, Inc. v. Phillips*, 2009 WL 10687806, at *3 (D. Minn. Jan. 16, 2009) (finding a privilege log inadequate because “[i]t is dominated by legal conclusions rather than useful factual descriptions of the withheld documents. The log’s document descriptions are replete with strings of loaded buzz phrases, such as ‘legal advice,’ ‘in anticipation of litigation,’ ‘in connection with rendering legal advice,’ and ‘communication to further common interest,’ but do not provide sufficient objective detail allowing fair assessment of those conclusions”); *United States ex rel. Schutte v. Supervalu, Inc.*, 2017 WL 1381651, at *2–3 (C. D. Ill. Apr. 17, 2017) (privilege log must include “[a] brief description or summary of the content of the document or communication” and a description of “[h]ow the document or communication satisfies the asserted privilege or privileges” as well as “[t]he name or names of the person or persons who prepared the document”).

As described above, BSC agreed to amend its June 14th Privilege Log, implicitly recognizing the deficiencies in that log. Even though many of the inadequacies that Relator pointed out in the June 14th Privilege Log also exist in the January 3rd Privilege Log, BSC has refused to amend its January 3rd Privilege Log on the grounds that Relator has waived his right to challenge that log. In support of its position, BSC did not provide any authority holding that a

challenge to a privilege log for inadequacy must be made within a certain amount of time. Instead, BSC cited to a case where a court ruled that an expert report should be excluded because it was produced after the discovery deadline in the case had passed. *See Anchor Wall Sys. V. Rockwood Retaining Walls, Inc.*, 252 F. Supp. 2d 838, 840–41 (D. Minn. 2002). The *Anchor Wall* case is clearly distinguishable from the present dispute, but its discussion of the discovery deadline points to the relevant inquiry, which is whether the challenge at issue was raised during the period of active discovery.

The Amended Scheduling Order (Dkt. 137) signed by Your Honor provides that “all non-dispositive motions . . . including those which relate to fact and expert discovery . . . shall be served, filed and HEARD by [January 27, 2020].” That same Order provides that “[a]ll fact discovery . . . of any kind shall be commenced in time to be completed by [July 30, 2019]”. Relator served the Requests for Production to which the January 3 privilege log relates in April 2018 (well over a year before the July 30, 2019 discovery deadline). In May 2018, BSC produced to Relator the documents it had previously produced to the Government. However, and notwithstanding BSC’s legal obligation under FRCP 26(b)(5)(A) to timely provide a privilege log, BSC failed to even advise Relator that the log already existed. Operating in the dark, and some six months later, Relator began to suspect that documents had been withheld on privilege grounds. Only after Relator requested a log (in December 2018) did BSC produce one (in January 2019). But that log only addressed the May 2018 production, and not any subsequent productions. Consequently, Relator sought BSC’s agreement to provide rolling privilege logs as each production was made. BSC agreed. But BSC failed to stand by that agreement for several months, and instead issued one final privilege log on June 14, 2019 for all productions between October 2018 and May 2019. Relator promptly provided BSC detailed objections to the both the January and June logs, only to

have BSC claim that it was Relator, and not BSC, who had failed to act in a timely fashion, and that thereby, Relator somehow “waived” his right to object to the contents of BSC’s January 3rd Log.

Turning to the merits of BSC’s “waiver” argument, the present motion to compel is scheduled for hearing before the Court on July 16, 2019, which is prior to the July 30, 2019 fact discovery deadline and more than six months before the January 27, 2020 deadline for non-dispositive motions relating to fact discovery. *See Fair Isaac Corp. v. Experian Info. Solutions, Inc.*, 2009 WL 10677528, at *11 (D. Minn. 2009) (explaining that the deadline for bringing a motion to compel is the scheduling order’s deadline for non-dispositive motions regarding fact discovery: “Pursuant to this Court’s Pretrial Scheduling Order, the deadline for bringing non-dispositive motions (i.e., served, filed and HEARD) was January 5, 2009. However, [the plaintiff] did not file its motion to compel, along with the supporting materials, for more than a month after that deadline and the hearing did not take place for almost two months after the deadline.”).

As Relator’s motion to compel is timely, and as BSC cannot seriously contend that its January 3rd Privilege Log is adequate for purposes of Federal Rule of Civil Procedure 26(b)(5)(A) given that it is already agreed to amend its June 14th Privilege Log in relation to the same sort of deficiencies, this Court should order BSC to amend its January 3rd Privilege Log. In the alternative, the Court should order that BSC has waived privilege for all documents appearing on the January 3rd Privilege Log for which BSC has inappropriately refused to provide sufficient privilege log entries. *See Vazquez-Fernandez v. Cambridge College, Inc.*, 269 F.R.D. 150, 160 (D. P. R. 2010).

CONCLUSION

For the reasons described above, the Court should compel Defendant BSC to produce to Relator a privilege log that will allow Relator and the Court to determine whether BSC’s assertions

of privilege have merit, or, in the alternative, the Court should compel BSC to produce the underlying documents over which it claims privilege.

Dated: July 2, 2019

Respectfully submitted,

BERGER & MONTAGE, P.C.

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CERTIFICATE OF SERVICE

I certify that on July 2, 2019, I caused the foregoing document to be filed via the Court's CM/ECF electronic filing system, which will provide an electronic copy to all counsel of record.

By: /s/ Daniel R. Miller